

K201342 HANAROSTENT Trachea/Bronchium (CCC)Dec 31, 2020
225 days to decisionK201342 · Product code: **JCT** · Anesthesiology
Source: <https://www.510kdatabase.net/k201342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Tracheal, Expandable (JCT)
Date received	May 20, 2020
Decision date	Dec 31, 2020
Days to decision	225 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	M.I. Tech Co., Ltd.
Location	Deerfield, IL, US
Contact	Inae Kim
510(k) history	14 submissions · 11 cleared · 2008-2025

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